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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,967	07/10/2003	Willard M. Welch	PC11002B	4135

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EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,967	WELCH ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The terms "preferably" and "eg." in the claims are improper since its not clear what is being claimed-subject before or after said terms.

2."Containing" in the R2-R5 definitions is open-ended language and as such implies more than what is positively recited. "Having" is suggested.

3.Many of the species in claim 4 appear to be outside the scope of main claim 1 at R1 definition. See 2nd species. Where is hydroxyalkyl claimed as R1? Also, see 3rd-5th species on p.22. The first of these is not a heteroaryl. The remaing two are not within the scope of "C1-C6 alkyl" recited in main claim 1. Many other examples exist. See the aliphatic nitriles recited as well as quinoline species.

5. Composition claims 5 and 7 are substantial duplicates as they embrace the same scope of active ingredients. Different (although all uses appear to be the same) intended uses in claims are given no material weight. Note In re Tuominen 213 USPQ 89.

6.Method claims 6 and 8 also appear to be substantial duplicates as the same uses are covered as well as scope of active ingredients.

Claims 1,3-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1.Additionally applicants provide no reasonable assurance that the compounds of the scope claimed will share the minimum activity needed to practice the invention. Specification identifies no particular compounds as having been tested. The scope of heteroaryl moieties embraced from a reading of the specification includes any and all 5-6 membered rings having N,O and/or S atoms in any array and up to 4 times both fused and unfused. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art.

3. Treating all disorders in method claims 6- 8 as well as in composition claims 5 and 7 is not adequately enabled based solely on 5 HT-7 agonistic activity urged but not reported for instant compounds. The notion that simply having the ability

to be an agonist at 5HT7 receptor sites will enable the treatment of all these disorders has not been substantiated. While there exists a reasonable if not absolute correlation for treating uses such as depression, anxiety and sleep disorders, see Mullins, (Medline abstract) or Vanhoeneker, both references provided in parent, there is no art-recognized evidence that scope claimed can be treated. In fact Vanhoeneker emphasizes that research in the area of 5-HT7 receptors is only in the early stages of development. Tests described in specification appear to only screening protocols which is not indicative of **in vivo** efficacy. Note Hoffman v. Klaus 9 USPQ 2d 1657 regarding the standard of testing that is necessary to establish the likelihood of **in vivo** use. Also see Ex parte Powers 220 USPQ 925. Thus given the state of the prior art coupled with the breadth of the claims , the level of unpredictability in the art vs. the lack of direction (i.e. working examples) provided as to what other substituents might work, this rejection is being applied. These are all factors considered in the Wands decision cited in the MPEP 2164.01(a).

The disclosure is objected to because of the following informalities: The 2 US provisional applications relied on for 119(e) benefit are not mentioned in the specification on p.1. See MPEP 1302.04. Also parent case under 35 USC 120 is not mentioned. Note Hovlid v. Asari 134 USPQ 162.

Appropriate correction is required.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The new fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

E Bernhardt

EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600